

Survey for HIV Antibodies and Antigen (HIV)

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Heidelberg

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Instructions for Use

Notes:

The samples should be considered as potentially infectious. The usual precautions in the laboratory for potential hazardous samples apply for these samples. They should be handled by trained personnel only.



WARNING: Contains methylisothiazolones.
H317 May cause allergic skin reaction.



This product contains human source material and should be considered as potentially infectious.

Various tasks of the proficiency testing scheme may occasionally be given over to qualified subcontractors. However, ESfEQA is responsible to the participants for the subcontractor's work.

Results from sample analysis may only be disclosed to colleagues from other laboratories after the testing period has been concluded.

By registering for and participating in this EQA participants agree to accept the general terms and conditions of ESfEQA GmbH. These can be retrieved online at www.esfeqa.eu

1. Intended Use

The samples are intended for use as qualitative control material for External Quality Assessment (EQA) in medical laboratories for the following analytes:

anti-HIV 1/2
HIV p24 Ag

Please note that the ESfEQA HIV survey is designed for assays that detect HIV antibodies and HIV antigen separately. For combo tests (e.g. HIV 4th generation assays) that detect HIV antibodies and HIV antigen simultaneously we recommend the enrollment in the ESfEQA INF survey.

2. Product Description

The samples are liquid, ready-to-use.

3. Storage and Stability

The samples should be stored upright at 2-8 °C. They are stable at least until the deadline for data submission as indicated below.

4. Sample Preparation and Analysis

For handling precautions, refer to the "Technical Rules for Biological Agents - Protective measures for activities involving biological agents in laboratories - TRBA 100" (available at <https://www.baua.de/EN/Service/Legislative-texts-and-technical-rules/Rules/TRBA/TRBA-100.html>), or to "Biosafety in Microbiological and Biomedical Laboratories - CDC/NIH - Latest edition", or to the regulations currently in use in your country.

Allow the sample to equilibrate to room temperature for 15 minutes prior to testing. Directly before use, agitate the sample by gently inverting the vial several times.

Attention: Despite careful selection and preparation of EQA samples from native human material, individual lots may occasionally contain fibrin particles and clots may be observed in these samples. In such a case, we recommend that participants centrifuge the sample for 10 minutes at high speed (e.g. 10,000 rcf) to sediment the fibrin particles/clot. The supernatant can then be transferred to a new container/cup for subsequent analysis on the test system.

All samples should be treated the same way as patient samples and analyzed in accordance with the instructions of the instrument and reagent manufacturer.

5. Dates and Submission of Test Results

Testing Periods: Please refer to the sample labels. Results can be submitted anytime within the testing period indicated on the sample labels.

Please submit your results electronically to ESfEQA at <https://teqa-labv2.esfeqa.eu>.

Contact your local distributor of ESfEQA programs or ESfEQA directly if you need assistance with registration in TEQA. Alternatively, though not preferred, use the result form provided on the ESfEQA website. In both cases indicate the instrument and method used for the analysis of the samples.

6. Deadline for Data Submission

The deadlines for submitting results are indicated on the sample labels (time zone GMT +1).

7. Reports and Certificates

The data will be evaluated by ESfEQA. The individual laboratory reports and certificates can be retrieved online at <https://teqa-labv2.esfeqa.eu>.

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